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CERTIFICATE OF MAILING

I hereby certify that this RESPONSE is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on this 4th day of January, 2005

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Wendy A. Frick

Signed: Wendy A. Frick

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Hazen, et al.	Examiner: Nolan, Patrick J.
Serial No.: 10/039,753	Art Unit: 1644
Filed: January 2, 2002	
For: **MYELOPEROXIDASE, A RISK INDICATOR FOR CARDIOVASCULAR DISEASE**	Attorney Docket No.: 26473/04177

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Restriction Requirement, applicants elect the claims in Group I, claims 1-16 drawn to a test for detecting cardiovascular disease. In response to the election of species, applicants hereby elect MPO mass. The claims that read on the elected species include claims 1, 7, 8, 9, 10, 16, as shown in the attached preliminary amendment, as well as new claims 23, 25, 26, and 27, as shown in the attached preliminary amendment. The election is with traverse.

The Office carefully makes the case that the claims of Groups I, II, and III are **distinct**:

> Inventions I, II, and III are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP § 806.05(h)). In the instant case the kit can be used in either the method of Group I or Group II.

> Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the invention of Group II requires the testing of the efficacy of a therapeutic regimen in already diagnosed patients, while the invention of Group I is used to do the initial diagnosing, so the population are different as well as the products encompassed by both methods.
>
> (Office Action, page 2, paragraphs 3 and 4).

Applicant submits that restriction is not proper in this instance. M.P.E.P. § 803 states the requirement for a **proper** restriction. There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; **and (B) There must be a serious burden on the examiner if restriction is required**. (M.P.E.P. § 803, citations omitted, emphasis added.) Thus, there are **two** requirements for restriction: distinctness **and** a **serious** burden. Both are required; distinctness without a serious burden is not sufficient to justify restriction. Indeed, section 803 explicitly states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

Applicant respectfully submits that restriction is not proper in this case. While the claims of Groups I, II, and III may satisfy the Office's requirements for distinctness, their consideration would not result in a **serious** burden on the Office. Thus, Applicant respectfully requests that the Office consider Groups I, II, and III (i.e., claims 1-27 as shown in the attached amendment) together. If the Examiner wishes to propose a new grouping of the claims, for example grouping all the method claims and the kit claims the recite MPO mass or MPO activity together, he is encouraged to contact the attorney of record, Ms. Pamela Docherty, at her direct dial number (216) 622-8416.

Respectfully submitted,

Date: Jan. 4, 2005

By: Kristin J. Frost

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